

This document is an English-translated version of an attachment of notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

This English version is intended to be a reference material to provide convenience for users.

In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Brimonidine tartrate

Brimonidine tartrate/brinzolamide

Ripasudil hydrochloride hydrate/brimonidine tartrate

June 11, 2024

Therapeutic category

Agents for ophthalmic use

Non-proprietary name

Brimonidine tartrate

Brimonidine tartrate/brinzolamide

Ripasudil hydrochloride hydrate/brimonidine tartrate

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <u>Corneal opacity with neovascularisation, etc. may occur following administration of this drug. Patients should consult their doctor periodically, and they should be carefully monitored. In addition, they should be adequately instructed to seek medical attention immediately if they have any subjective symptoms such as hyperaemia, reduced visual acuity, or blurred vision.</u>
11. ADVERSE REACTIONS (N/A)	11. ADVERSE REACTIONS <u>11.1 Clinically Significant Adverse Reactions</u> <u>Corneal opacity</u>

[References] Maruyama,Y.,et al.:Cornea 2017;36:1567-1569

Tsujinaka,A.,et al.:Acta Ophthalmol. 2019;97:e948-e949

Manabe,Y.,et al.:Eur.J.Ophthalmol. 2020;30:NP23-NP25

Chikama,T.,et al.:Ocul.Immunol.Inflamm. 2023;31:1842-1847

Note: Brimonidine tartrate is designated as a drug requiring preparation of a Drug Guide for Patients.

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.